

Applicant: Huston et al.
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Filed: February 26, 1991
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-- This application is a divisional application of USSN
462,297, filed December 28, 1989, which is a continuation
application of USSN 028,484, filed March 20, 1987, now abandoned.
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In the Claims:

Cancel claims 1-26 were previously canceled. Claims 39-46
are hereby canceled without prejudice.

REMARKS

Claims 27-38 are pending in the above-captioned patent application. In response to a restriction requirement under 35 U.S.C. §121, applicants have elected claims 27-38 and have canceled claims 39-46 and reserved the right to file a divisional application containing claims 39-46.

Claims 27-38 cover a fused polypeptide produced by an organism by expression of a recombinant DNA, the polypeptide including a first sequence of amino acids including a leader sequence, a hinge region, and at least one amino acid defining a cleavage site recognizable and cleavable by a selected cleavage agent, the hinge region being cysteine-free and including at least two amino acids which promote cleavage by the cleavage agent at the cleavage site. The polypeptide also includes a second sequence of amino acids linked to the first sequence and defining a selected target polypeptide. The cleavage site of the fused polypeptide is a favored site for cleavage upon treatment of the fused polypeptide with the cleavage agent when the fused

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polypeptide is disposed in solution and the second amino acid sequence is disposed in its tertiary conformation.

Rejection under 35 U.S.C. §103

Claims 27-38 were rejected under 35 U.S.C. §103 as being obvious over Cousens et al. in view of the Cohen et al. patent. Applicants traverse the rejection.

Cousens et al., U.S. Patent No. 4,751,180, is not prior art to claims 27-38 of the instant application, since the subject matter claimed in claims 27-38 was first disclosed in applicants' parent application, USSN 462,297, filed December 28, 1989, which is a continuation application of USSN 028,484, filed March 20, 1987, now abandoned. USSN 462,297 has issued as U.S. Patent No. 5,013,653. The specification has been amended to reflect the continuity of the pending application with the abandoned parent application.

Applicants enclose herewith a 37 C.F.R. 1.131 declaration which states that applicants invention, as claimed in claims 27-38 was invented prior to the March 28, 1986 filing date of the Cousens et al. patent. Applicants have reviewed the file history of the USSN 845,737 patent application which issued to the Cousens '180 patent and which is a continuation-in-part application of USSN 717,209, now abandoned. The parent application contains no information about the hinge region of the fusion peptide. In fact, the information disclosed in col. 4, lines 16-47 of the Cousens '180 patent is not disclosed in the

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abandoned parent application. Thus, for the hinge region information in the Cousens patent, the priority date is the March 28, 1986 filing date of the continuation-in-part application.

Claims 27-38 are not obvious over the cited references because neither of the cited references discloses a recombinant fusion polypeptide including a leader sequence, a hinge region, at least one amino acid defining a cleavage site, and a target polypeptide, whereby the cleavage site is favored upon cleavage when the fusion polypeptide is disposed in aqueous solution and the target polypeptide is disposed in its tertiary conformation.

Applicants submit that the claims are in condition for allowance and such action is speedily requested. If there are any credits or debits, please credit or debit Deposit Account No. 20-0531.

Respectfully submitted,

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